requirement for adequate and well-controlled studies is waived as provided in §314.111(a)(5)(ii) of this chapter.

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(vii) Suggests, on the basis of favorable data or conclusions from nonclinical studies of a prescription drug, such as studies in laboratory animals or in vitro, that the studies have clinical significance, if clinical significance has not been demonstrated. Data that demonstrate activity or effectiveness for a prescription drug in animal or in vitro tests and have not been shown by adequate and well-controlled clinical studies to pertain to clinical use may be used in advertising except that (*a*), in the case of anti-infective drugs, in vitro data may be included in the advertisement, if data are immediately preceded by the statement ''The following in vitro data are available but their clinical significance is unknown'' and (b), in the case of other drug classes, in vitro and animal data that have not been shown to pertain to clinical use by adequate and well-controlled clinical studies as defined in §314.111(a)(5)(ii) of this chapter may not be used unless the requirement for adequate and well-controlled studies is waived as provided in §314.111(a)(5)(ii) of this chapter.

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PART 203—PRESCRIPTION DRUG MARKETING

Subpart A—General Provisions

Subpart B—Reimportation

Subpart C—Sales Restrictions

Subpart D—Samples

Subpart E—Wholesale Distribution

Subpart F—Request and Receipt Forms, Reports, and Records

Subpart G—Rewards

AUTHORITY: 21 U.S.C. 331, 333, 351, 352, 353, 360, 371, 374, 381.

SOURCE: 64 FR 67756, Dec. 3, 1999, unless otherwise noted.

Subpart A—General Provisions

§203.1 Scope.

This part sets forth procedures and requirements pertaining to the reimportation and wholesale distribution of prescription drugs, including both bulk drug substances and finished dosage forms; the sale, purchase, or trade of (or the offer to sell, purchase, or trade) prescription drugs, including bulk drug substances, that were purchased by hospitals or health care entities, or donated to charitable organizations; and the distribution of prescription drug samples. Blood and blood components intended for transfusion are excluded from the restrictions in and the requirements of the Prescription Drug Marketing Act of 1987 and the Prescription Drug Amendments of 1992.

§203.2 Purpose.

The purpose of this part is to implement the Prescription Drug Marketing Act of 1987 and the Prescription Drug